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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,344	JIRA ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-12* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-8-05, 5-9-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1 and 3-12 are pending in the application. In the prior action, the Final action mailed on February 8, 2005, claims 1-122 were pending, with claims 10-12 withdrawn as to non-elected inventions and claims 1-9 rejected.

2. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 8, 2005 has been entered.

3. The Response accompanying the RCE amended claims 1 and 3-9; and cancelled claim 2. Claims 1 and 3-9 are under consideration.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on June 8, 2005, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

While the IDS of May 9, 2005 is also in compliance, each of the references cited in this IDS are also made or record and considered in the IDS of June 8, 2005. Thus, the May 2005 IDS has not been separately considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(Prior Rejection- Withdrawn)** Claims 3 and 4 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear what the scope of an immunogenic composition comprising a "reduced viral pathogen" was. In view of the amendment of the claims to read on viral pathogens denatured at higher than 60° C, the rejection is withdrawn.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Maintained)** Claims 3-9 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising an inactivated influenza virus, does not reasonably provide enablement for vaccine compositions, or compositions inducing immunity against, any viral pathogen. The claims have been amended to read on compositions that elicit an immune response to a viral pathogen "in a host in need thereof." Because the claim indicates that the host is in need of the immune response, and as there would be no such "need" unless the response induces a therapeutic effect, the rejection is maintained on the same grounds as previously described, even though it is noted that the claims have been amended to refer to an immune response rather than the induction of immunity. The rejection is withdrawn from claim 4 as this claim is currently under consideration only to the extent that it reads on the elected invention (influenza virus antigens).

In traversal of the rejection, the Applicant provided examples of compositions that have shown some therapeutic benefit. However, it is not clear from these disclosures either that 1) a common means of producing the antigens was used or 2) what the components or means of producing each of the indicated antigenic compositions is. With respect to the elected invention, influenza antigens, the Declaration shows some efficacy in chickens. Further, as indicated by the teachings of Meruelo et al. (U.S. 5,506,271) (see rejection under 35 U.S.C. 103(a) below), the Applicant appears enabled for the immunization against influenza using the claimed compositions.

However, as a further example of the claimed invention, the Applicant refers to certain results of HIV formulations disclosed in the application and in certain references identified in the Response. It is not clear from the application which of the multiple suggested HIV antigenic formulations was used in the results of Example 11. See e.g., pages 49, first 2 paragraphs, and pages 50-52 (disclosing three different modes of producing HIV antigens). More particularly, the art referred to by the Applicant on page 8 of the Response refers not to the use of any inactivated HIV generally, but to a specific formulation produced by a specific method. There has been no demonstration that any such inactivated composition would achieve the same results. As there is no demonstration of the use of solely the isolated virus, it is not clear that similar results would be achieved when the viruses are heat inactivated in the absence of the additional components.

While the application provides examples, it is not clear from those provided that any compositions comprising any viral pathogen denatured at higher than 60°C would be capable of inducing a protective or therapeutic response. The examples provided in the application and in the Declaration are informative, but are not sufficient to demonstrate enablement for the full

scope of the claimed invention. The rejection of the claims for exceeding the scope of enablement is therefore maintained.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **(Prior Rejection- Withdrawn)** Claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by Avtushenko et al., J Biotechnol 44: 21-28. Applicant traverses the rejection on the grounds that claims 1 and 2 require heat inactivation of the viral pathogen, and that the reference does not teach heat inactivation. In view of the amendment of pending claim 1 to require heat denaturation at higher than 60°C and Applicant's arguments therewith, and the cancellation of claim 2, the rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claims 3-5, and 7-8 were rejected under 35 U.S.C. 102(a) as being anticipated by Barrett et al. (WO 00/47222, see, U.S. Patent 6,635,246 for English translation of the specification of the reference). In view of the amendment of the pending claims to require heat denaturation at higher than 60°C and Applicant's arguments therewith, the rejection is withdrawn.

12. **(Prior Rejection- Withdrawn)** Claims 5-8 were rejected under 35 U.S.C. 102(b) as being anticipated by Waldman et al. (Am J Med Sci 292: 367-71). In view of the amendment of the pending claims to require heat denaturation at higher than 60°C and Applicant's arguments therewith, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. **(Prior Rejection- Withdrawn)** Claims 1-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over either Zakay-Rones et al. (WO 97/14434) or Dutcher et al. (U.S. Patent 3,060,094), either of these references in view of Smith et al. (U.S. Patent 6,245,532), or Avtushenko, and further in view of Sokoll et al. (U.S. Patent 6,623,764). In view of the amendment of the pending claims to require heat denaturation at higher than 60°C and Applicant's arguments therewith, the rejection is withdrawn.

15. **(Prior Rejection- Withdrawn)** Claims 5-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sokoll (supra). In view of the amendment of the pending claims to require heat denaturation at higher than 60°C and Applicant's arguments therewith, the rejection is withdrawn.

16. **(Prior Rejection- Withdrawn)** Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of either Barrett as applied above against claims 3-5, 7, and 8, Avtushenko as applied against claim 3-4, or Waldman as applied against claim 5-8. In view of the amendment of the pending claims to require heat denaturation at higher than 60°C and Applicant's arguments therewith, the rejection is withdrawn.

17. **(New Rejection)** Claims 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo et al. (U.S. 5,506,271). This claim is directed to compositions comprising a heat inactivated influenza antigen formulated for oral presentation, wherein the virus is inactivated at a temperature of greater than 60° C.

Meruelo teaches compositions comprising inactivated viral pathogens. Column 12. In describing methods for the inactivation of the viral pathogens, the patent teaches two methods "well-known in that art" that involve the heating of the pathogens to temperatures of greater than 60°C. Id, lines 45-49. The reference therefore renders obvious immunogenic compositions comprising viral pathogens inactivated at temperatures of greater than 60°C. Further, the reference also identifies a number of viral pathogens that may be used according to the disclose inventions. These include the influenza virus. Column 10,lines 57-63. The reference additionally teaches that the composition may be formulated for oral delivery, including in the forms of tablets or capsules. Columns 12-13. The reference therefore teaches compositions comprising a heat inactivated influenza antigen, wherein the virus is denatured at a temperature of at least 60 ° C.

18. **(New Rejection)** Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo as applied to claim 1 above, and further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494). These claims read on compositions such as those in claim 1 above, except that the claims require that the oral compositions are in the form of pills. The teachings of Meruelo have been described above. The reference teaches that the indicated antigens may be combined with (or without) additional adjuvants (col. 12, lines 53-56), and that they may be manufactured into compositions for oral delivery. Columns 12-13. However, while the reference identifies tablets and capsules as useful modes of delivery, the reference does not identify pills as such.

However, the teachings of Meruelo do, as described above, teach the administration of the antigens in oral formulations, and indicate that any known manner of manufacture may be used in the formulation of the disclosed antigens (col. 12, lines 56-59). Pills represent a known formulation recognized in the art as useful for oral immunogenic compositions. See e.g., Felici, column 4, lines 44-49, and Ooyama, page 3 (each recognizing pills as an alternative to tablets and capsules for oral vaccine formulations). It is additionally noted that each of the Felici and Ooyama indicate that influenza antigens are among those that may be administered using the described oral formulations. Felici, column 1 lines 33-44; and Ooyama, page 3 lines 6-12. Those of ordinary skill in the art would have had a reasonable expectation of success in the combination based on the teachings of Meruelo teachings the oral administration of the inactivated influenza, and the teachings of Felici and Ooyama indicating that pills are recognized means of administering such oral immunogens. Thus, the teachings of these references, in combination

with the suggestion of Meruelo render obvious the use of a pill formulation for the inactivated influenza.

Conclusion

19. No claims are allowed.

20. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Prince et al., U.S. 4,695,464. This patent teaches a composition comprising a heat inactivated viral antigen, wherein the antigen is inactivated at a temperature of over 60°C. However, the reference does not teach the denaturation of the entire virus, or the formulation of the antigen for oral administration or as a pill.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 8/9/05
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